IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2974 1:20-md-02974-LMM [1178]
This document relates to: Pauline Rickard Melody Braxton Alisa Robere	:	CIVIL ACTION NOs.: 1:21-cv-03861-LMM [68, 167] 1:22-cv-00490-LMM [60, 109] 1:22-cv-01583-LMM [70, 126]

ORDER

This multi-district litigation ("MDL") involves the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The matter is before the Court on a Motion to Exclude the Opinions of Stephanie Benight, Ph.D., from evidence offered in defense against claims asserted by bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere (collectively, "Plaintiffs"). On January 13, 2026, the Court entered an Order on the motion. Upon further consideration, the Court **VACATES** the initial Order and enters the following Order, nunc pro tunc.

I. BACKGROUND

Paragard is an IUD that is implanted into a patient's uterus by a healthcare provider. It is a T-shaped device that is made of low-density polyethylene ("LDPE") milled with barium sulfate and wrapped in copper. It is indicated for

intrauterine contraception for up to 10 years. The T-shaped Paragard base is designed to collapse for insertion and removal. It is supposed to be easy for a healthcare practitioner to remove the Paragard by gently pulling on attached threads.

Paragard has been approved and regulated by the FDA since 1984 without any significant design updates. Teva became the owner of the Paragard NDA in December 2008 and held it until the NDA was acquired by Cooper on November 1, 2017.[1]

Robere underwent placement of a Paragard in June 2011, Rickard had hers placed in May 2012, and Braxton had hers placed in November 2014. At the time Plaintiffs had their Paragards placed, there was nothing in the Warnings, Adverse Reactions, or Patient Information sections of the drug label about breakage, and each plaintiff expected for the removal of her Paragard to be simple and easy. But in each case—when Robere and Braxton had their Paragards removed in or around December 2019 and when Rickard had hers removed in August 2021—the Paragard was broken, and it was necessary for the plaintiff to have surgery to remove fragments of the Paragard.

[1] "Teva" or "Defendant" refers collectively to Defendants Teva Pharmaceuticals USA, Inc.; Teva Women's Health, LLC; and Teva Branded Pharmaceutical Products R&D, Inc. "Cooper" refers to Defendant CooperSurgical, Inc., which was granted summary judgment of Plaintiff's claims in other Orders. See Dkt. Nos. [116, 137, 138].

Dr. Benight has a dual Ph.D. in chemistry and nanotechnology and is currently President and Principal Scientist of Tactile Materials Solutions, a consulting company focused on polymers, chemistry, and advanced materials. Dkt. No. [56-6] at 8. Dr. Benight conducted four tests on pre-implant samples of the Paragard T-base: (1) differential scanning calorimetry ("DSC") to determine the degree of crystallinity; (2) tensile testing to determine the tensile force the IUD can withstand; (3) scanning electron microscopy ("SEM") coupled with energy dispersive X-ray spectroscopy ("EDS") to test for any agglomeration of barium sulfate; and (4) manual mechanical manipulation involving holding the plastic tee in the inserter for various lengths of time, followed by release and visual microscopy inspection to see if cracks or breakage occurred. Id. at 62-88.

Dr. Benight offers the following opinions in Teva's defense against Plaintiffs' claims: that there is no evidence of oxidative degradation in the polyethylene used in Paragard; that mechanical testing of exemplar Paragard T-bases showed that they performed as expected—they exceeded minimum tensile strength requirements, showed no barium sulfate clumping or change in crystallinity at the arm-stem juncture, and had no breakage from manual manipulation; that the Dupont 20 and Dupont 2005 polyethylene approved for use in the Paragard T-base are effectively the same for Paragard's purposes and that any reported differences are not expected to yield a change in performance or oxidative degradation; and that there is no data supporting claims of oxidation

during manufacture. Id. at 11-12.[2] Dr. Benight also questioned why, if Paragard were pervasively degrading in the body, pregnancy rates would not be drastically increased. Id. at 12.

Plaintiffs seek to exclude Dr. Benight's opinions and testimony under Rule 702 of the Federal Rules of Evidence. Dkt. No. [68]. They argue that Dr. Benight has not shown that her experience qualifies her to opine on in vivo oxidation of polymers and medical devices; that her methodology regarding her opinion on in vivo oxidation is scientifically unreliable and disconnected from the literature; that her testing of exemplar Paragards does not comply with International Organization for Standardization Standards ("ISO"); that her testing is irrelevant because she tested newer and unused Paragard exemplars without specifying what years they were produced, the conditions under which they were stored, or the LDPE they contained; and that her opinions on pregnancy rates and contraceptive efficacy are beyond her expertise and unrelated to breakage. Id. at 6.

The Court will first review the legal standards guiding adjudication of a motion to exclude evidence under Rule 702. It will then consider the parties' arguments in logical order.

[2] Unless otherwise noted, record citations are to the documents filed in Rickard v. Teva Pharms. USA, Inc., Civ. Case No. 1:21-cv-03861-LMM (N.D. Ga.).

II. LEGAL STANDARD

Federal Rule of Evidence 702 governs the admissibility of proposed expert evidence:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and,
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

The trial court, as the evidentiary gatekeeper, must determine that the testimony is "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Daubert v. Merrell Dow Pharm., 509 U.S. 579, 591 (1993) (quoting United States v. Downing, 753 F.2d 1224, 1242 (3d Cir. 1985)). The trial court must also "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137, 152 (1999).

The Eleventh Circuit has synthesized the existing rules into a three-part inquiry, instructing courts to consider whether: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the

methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998), reh'g and reh'g en banc denied, 172 F.3d 884 (1999).

With regard to the second factor, the Supreme Court explained in Daubert and its progeny that courts should serve a gatekeeping function in order to ensure the reliability of the methods employed by expert witnesses. 509 U.S. at 589. The Daubert inquiry specifically addresses the reliability of an expert's principles and methods. Daubert lists factors for courts to consider, including: (1) "whether [the theory or technique] can be (and has been) tested," (2) "whether the theory or technique has been subjected to peer review and publication," (3) "the known or potential rate of error," and (4) "general acceptance" of the theory in the field. Daubert, 509 U.S. at 593-94. Additional factors courts have used to assess reliability of expert methods include whether the opinion naturally flowed from an expert's research or was developed specifically for litigation, and whether an expert has improperly extrapolated from a scientifically founded proposition to an unfounded conclusion. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1312, 1314, 1321 (11th Cir. 1999).

But "expert testimony that does not meet all or most of the Daubert factors may sometimes be admissible." United States v. Brown, 415 F.3d 1257, 1268 (11th Cir. 2005). Indeed, reliability is meant to be a flexible inquiry for district courts, allowing them to determine which factors may be relevant and to apply only those factors which the court sees fit. United States v. Frazier, 387 F.3d 1244, 1262 (11th Cir. 2004). "The burden of laying the proper foundation for the admission of the expert testimony is on the party offering the expert, and admissibility must be shown by a preponderance of the evidence." Allison, 184 F.3d at 1306. However, "the proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable." Id. at 1312.

The trial court has a great deal of flexibility in the inquiry into the reliability of an expert. Daubert, 509 U.S. at 595. This flexibility includes "latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability." Kumho Tire, 526 U.S. at 152.

"In the end, although rulings on admissibility under Daubert inherently require the court to conduct an exacting analysis of the proffered expert's methodology, it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." Quiet Tech. DC-8, Inc. v. Hurel Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003) (internal citations

and quotation marks omitted). "Quite the contrary, 'vigorous cross-examination, presentation of contrary evidence and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" Id. (quoting Daubert, 509 U.S. at 596) (internal alteration omitted).

III. DISCUSSION

A. Whether Dr. Benight is qualified to opine on in vivo oxidative degradation and embrittlement of the Paragard

Plaintiffs argue that Dr. Benight's opinions regarding in vivo oxidating degradation and embrittlement of the Paragard should be excluded because she lacks a foundational background in biomaterials science and does not explain how the biomaterials experience she does have qualifies her to render such opinions. Dkt. No. [68] at 12-14. They also suggest that the Court should discount experience Dr. Benight has with vaginal and hernial mesh because the experience was gained through her work in other litigation. Id. at 14. The Court does not agree.

First, Plaintiffs supply no authority, and the Court knows of none, that requires it to ignore relevant experience because it was gained through work in litigation. Rather, courts have held that even where the expert primarily focuses on litigation consulting, that does not eradicate the expert's expertise. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 753-54 (3d Cir. 1994); In re Greater Se. Cmty. Hosp. Corp. I, No. 02-02250, 2007 WL 7230958, at *3 (Bankr. D.D.C. Jan. 3, 2007) ("To qualify as an expert, . . . Rule 702 does not require that the witness

possess non-litigation-related experience; rather, it requires that the witness possess sufficient knowledge, skill, experience, training or education to render him competent to testify on the matters he intends to address."). Thus, the fact that some of Dr. Benight's experience is derived from work as an expert witness to litigation is of no import here.

Second, Dr. Benight's testimony and expert report shows that she has significant education, training, and experience in plastics like those making up the Paragard T-base, including studying their degradation and embrittlement. As Defendant points out, Dr. Benight holds a bachelor's degree in chemistry from Stanford University and a Ph.D. in chemistry, with a materials focus, and a dual Ph.D. in nanotechnology from the University of Washington. Dkt. No. [56-6] at 8. She also completed postdoctoral work as a research associate scientist at Stanford and has taken courses with recognized experts in biomaterials. Id.; Deposition of Stephanie Benight, Ph.D. ("Benight Dep.") at 66-67, 165. Besides serving as the president and principal scientist of Tactile Materials Solutions, she has also served as a visiting scientist at the University of Washington for the past four years; is active in professional organizations such as the American Chemical Society and ASTM International (formerly known as the American Society for Testing and Materials); and has served on relevant committees with those organizations. Dkt. No. [56-6] at 8-10.

Dr. Benight has 20 years of research experience in chemistry and materials, both in academic and industrial settings, with a particular emphasis on polymers such as polypropylene and polyethylene. Id. at 8. Her professional experience includes analysis and testing of medical devices, both in litigation and consulting, with direct work on polyolefin-based devices. Benight Dep. at 80-81, 135-37. This experience includes investigating failures of adhesives and plastics in products, including medical devices, and assessing whether polymer degradation has occurred. Dkt. No. [56-6] at 8; Benight Dep. at 80-81. She has also conducted research and published on the degradation and oxidation of polypropylene-based polymer mesh medical devices and is familiar with the "foreign body response" as it relates to polymer implants. Dkt. No. [56-6] at 8; Benight Dep. at 103, 164-67.

Dr. Benight is skilled in analytical techniques for polymer characterization, such as gas chromatography mass spectrometry ("GC-MS"), liquid chromatography tandem mass spectrometry ("LC-MS/MS"), Fourier transform infrared spectroscopy ("FTIR"), and nuclear magnetic resonance spectroscopy ("NMR"), which are used for investigating material behavior, including detecting polymer degradation. Id. at 9. She has provided consulting and expert services in over one hundred projects involving polymers, adhesives, and coatings, including failure analyses in the medical device field. Id.

Dr. Benight has been specifically engaged as an expert in litigation involving Paragard, focusing on the characterization of its polymer components. Id. at 13. She explains that she performed independent testing of the material properties of exemplar Paragard products; reviewed literature and company documents produced as part of the litigation, and reviewed the report of Plaintiffs' expert witness Jimmy Mays, Ph.D. Id. at 13, 62.

Given this evidence of Dr. Benight's knowledge, experience, training, and education in polymers, the Court finds that she is qualified under Rule 702 to opine regarding oxidative degradation, or the lack thereof, in the Paragard base material both inside and outside the body.

B. Admissibility of testing-related opinions

The Court next turns to Plaintiffs' argument that Dr. Benight's independent testing of the Paragard exemplars must be excluded. See Dkt. No. [68] at 21-26. They argue, among other things, that the testing should be excluded because Dr. Benight tested only unused, never-implanted Paragards without specifying what years they were produced, the conditions under which they were stored, or the LDPE they contained. Id. at 21, 24-26.

For the most part, the Court agrees with Plaintiffs. It is true that oxygenation testing could be relevant, even of a never-implanted Paragard. While the oxidation of a new Paragard is a minor issue in this case, Plaintiffs have made clear that they intend to offer testimony of their materials expert, Jimmy W.

Mays, Ph.D., to show that Teva's design choice to switch from one FDA-approved polymer to another—Dupont 2005 to Dupont 20—was problematic because Dupont 20 is more prone to oxidation, and the products were stored in a way that exposed them to oxygenating catalysts, light and heat. Testing disproving or disproving this theory therefore could be helpful.

However, Defendant has not responded to Plaintiffs' argument that Dr. Benight did not record which LDPE made up the exemplars she used in her testing. Thus, it is not clear that the results of the crystallinity, tensile, and mechanical-manipulation tests of the new Paragards in fact address Dr. Mays' theory. As such, they carry a high risk of misleading the jury.

On the other hand, nothing suggests that the dispersion of barium sulfate changes over time or varies according to the LDPE used in the exemplar product, and the examination of the T-bases for agglomeration of barium sulfate responds directly to Dr. Mays' opinion that high barium sulfate content can lead to poor dispersal and create stress points that act as crack initiators. See Dkt. No. [147] at 14. The record also indicates that the mix of barium sulfate in the T-base has remained constant since Paragard's introduction, which suggests that the year of manufacture is irrelevant. And Plaintiffs offer no other reason Dr. Benight should not be able to testify regarding her testing for barium sulfate agglomeration.

Accordingly, Dr. Benight may testify regarding her tests for barium sulfate agglomeration, but the remainder of her testing does not have a reliable foundation and thus cannot be presented at trial.

C. Whether Dr. Benight's methodology is scientifically reliable

Plaintiffs also argue that Dr. Benight's opinions should be excluded because there is no peer-reviewed basis for her opinion that the Paragard is not degrading in vivo; because her opinions are allegedly internally inconsistent; and because she has not presented an alternative explanation for Paragard breakage. Dkt. No. [68] at 14-21. The Court does not agree.

Dr. Benight appears to have done essentially what Dr. Mays did, which is to review peer-reviewed literature, company documents, and other relevant evidence in light of her education, training, and experience. While Dr. Benight cited one weak source for her opinion that polyethylene does not degrade over time, it is not the only source she cited for that principle. See Dkt. No. [56-6] at 14. Thus, the Court does not find the testimony excludable on that ground.[3] Inconsistencies in her testimony, to the degree that there truly are any, go to the weight of her testimony rather than its admissibility. Quiet Tech. DC-8, Inc., 326 F.3d at 1345. And as the Court explained in its Order on Defendant's motion to exclude the testimony of Dr. Mays, "an expert is not required to address all

[3] The Court made similar decisions in its Order on Defendant's motion to exclude the testimony of Dr. Mays. See Dkt. No. [147] at 12, 14.

alternative theories." Waters v. AIG Claims, Inc., 608 F. Supp. 3d 1120, 1135 (M.D. Ala. June 22, 2022) (citing Fuller v. SunTrust Banks, Inc., No. 1:11-CV-784, 2019 WL 5448206, at *20 (N.D. Ga. Oct. 3, 2019)).

These issues invite rigorous cross-examination, not exclusion. The Court therefore finds no basis in these arguments for excluding any of Dr. Benight's testimony.

D. Opinions on pregnancy rates

Finally, Plaintiffs argue that Dr. Benight's opinion on the relationship between breakage and pregnancy rates is speculative, unsupported by scientific basis, irrelevant to the case, and beyond the scope of Dr. Benight's expertise. Dkt. No. [68] at 26-29. This argument is well taken.

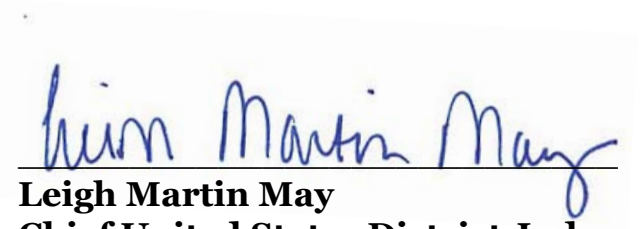
First, it is not even clear that Dr. Benight offered an opinion about a relationship between breakage and pregnancy rates. Rather, she admits that she "posed a question, not a statement." Benight Dep. at 156. Second, it is not at all apparent that breakage in fact affects the contraceptive mechanism of the Paragard. Third, Dr. Benight admits that the contraceptive efficacy of a broken Paragard is beyond her expertise. Benight Dep. at 158-59.

Thus, so much as Dr. Benight's comment about the contraceptive effect of a broken Paragard can be taken as an opinion, she did not have the necessary expertise to render it. Dr. Benight therefore cannot testify regarding the contraceptive effect of a broken Paragard.

IV. CONCLUSION

In accordance with the foregoing, the prior Order on Plaintiffs' Motion to Exclude the Opinions of Stephanie Benight, Ph.D., from evidence in the bellwether cases is **VACATED** and replaced with this Order, nunc pro tunc to January 13, 2026. The motion to exclude is **GRANTED IN PART AND DENIED IN PART**, as set out above.

IT IS SO ORDERED this 16th day of January, 2026, nunc pro tunc to January 13, 2026.



Leigh Martin May
Chief United States District Judge